

Trial Day 1
Volume 1 of 2
November 12, 1997

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

GLAXO WELLCOME INC., ET AL.)
Plaintiffs)
v.) Civil Docket No. AMD-96-455
PHARMADYNE CORPORATION, ET AL.) and
Defendants) Civil Docket No. AMD-96-1853
) (Consolidated)
)

Baltimore, Maryland
November 12, 1997
10:00 a.m.

The above-entitled matter came on for trial before
The Honorable Andre M. Davis

A P P E A R A N C E S

On Behalf of the Plaintiffs:
Stephen Judlowe, Esquire
John Henry Lewin, Jr., Esquire
Brian P. Murphy, Esquire
Robert Gibbons, Esquire
Regina Ambery, Esquire
Jason Lief, Esquire

On Behalf of the Defendants:
James Rubin, Esquire
Alan H. Bernstein, Esquire
Robert S. Silver, Esquire
John M. Seeberger, Esquire
Deborah K. Besche, Esquire

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1 discovery. It was considered a very important medical
2 discovery.

3 Q Okay. Would you continue with the rest of Exhibit 26 now,
4 please.

5 A Yes. Because the Burimamide wouldn't absorb into the body,
6 they looked at other analogues of this molecule. You will see
7 some similarities and some differences between the first
8 chemical structure and the second.

9 They found another drug called Metiamide. That caused bone
10 marrow suppression, which is a serious side effect and can
11 cause death. So, the trials of that drug were halted, and the
12 drug was abandoned.

13 They subsequently developed the drug Cimetidine which, as I
14 have already mentioned, was approved in the United States in
15 1977. It was an important medical advance. It fit the lock.
16 It was useful to patients because they did not have to have
17 surgery or the terrible complications of ulcer disease.

18 But it did have some side effects. There were side
19 effects. It interacted with the breakdown of other drugs in
20 the body if one needed to take more than one medicine. It also
21 had some endocrine side effects, causing breast formation in
22 males and impotence and effects such as that.

23 The final drug on the chart, Ranitidine, had --

24 Q Let me stop you there.

25 You have identified it by the chemical name, Cimetidine.

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1 What was the popular name the drug was sold under?

2 A It was sold as Tagamet in the United States. And that was
3 the name in most other countries as well.

4 Q Did Tagamet, notwithstanding the side effects that you have
5 identified, become a large-selling drug?

6 A It became the largest selling drug of all time in the early
7 1980s, more than any drug or any disease of any class. It
8 entered the Guinness Book of Records for that achievement. So,
9 it was an important drug in its time.

10 Q Finally, what is shown in blue?

11 A That is the chemical structure of Zantac or Ranitidine.
12 The important discovery here was that James Black believed that
13 he needed that yellow, what we call an imidazole nucleus in the
14 molecule.

15 THE COURT: Help the reporter, please.

16 THE WITNESS: I-m-i-d-a-z-o-l-e.

17 A Imidazole describes the yellow ring structure in the
18 molecule. That ring structure occurs in the histamine
19 molecule, and it also occurs in the first three drugs. Black
20 believed that it was absolutely essential to have that ring
21 structure.

22 Chemists at Glaxo at that time tried multiple ring
23 structures and discovered that you could even put a benzene
24 ring in there and still get the key to fit in the lock.

25 The ring that was selected was a furan ring, which is shown

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1 there, which is chemically quite different from the ring seen
2 in the three other drugs. That change and other changes in the
3 molecule enabled the scientists who developed this to get rid
4 of these side-effect problems with the drug interactions and
5 the sexual side-effect problems.

6 Ranitidine was also more potent, which allowed it to be
7 taken twice a day instead of four times a day as Tagamet was
8 taken then. So, that was another advantage of the product. It
9 was these advantageous that led to the -- I think I heard the
10 blockbuster used by counsel this morning -- that led to the
11 enormous commercial success of the molecule. It subsequently
12 displaced Tagamet as the world's leading selling drug.

13 Q Has Ranitidine become the largest selling drug cumulatively
14 over time?

15 A It was the largest selling drug of all time for ten years.

16 Q All right. Let's turn briefly to the subject of after
17 ranitidine hydrochloride was approved in the United States in
18 1983. Did Glaxo end its research and development on the
19 product?

20 A Far from it. I have spent the last 15 years developing
21 different formulations and testing them out. Not personally
22 developing the formulations, but testing them out medically in
23 patients. We have done more research since the drug was
24 launched in the United States than before on the product.
25 There is a possess of continual improvement with

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